NOV 2 2 2011 K103424

SIEMENS

510(k) Summary
For
SAFIRE

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

September 25, 2010

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. General Information

Importer / Distributor
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway, E-50
Malvern, PA 19355
Establishment Registration Number
2240869

Manufacturing Site
SIEMENS AG Healthcare Sector
Siemensstrasse 1
D-91301 Forchheim

2. Contact Person:
Mrs. Alicia Bustos-Juergensen
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway E-50
Malvern, PA 19355-1406
Phone:(610) 448-4056 Fax: (610) 448-1778

3. Device Name and Classification

Product Name:	SAFIRE
Propriety Trade Name:	SAFIRE
Classification Name:	Computed Tomography X- ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

4. Device Description

Siemens SAFIRE is a software option to for CT operating system SOMARIS/7. It provides an improved image quality. Reciprocally the use SAFIRE allows the physician to acquire scans with reduced radiation dose without reduction of image quality compared to today's standard.

5. Intended Use

SAFIRE is a CT reconstruction software. The end user can choose to apply either SAFIRE or the weighted filter back-projection (WFBP) to the acquired raw data.

Depending on the clinical task, patient size, anatomical location, and clinical practice, the use of SAFIRE can help to reduce radiation dose while maintaining Pixel noise, low contrast detectability and high contrast resolution. Phantom measurements showed that high contrast resolution and pixel noise are equivalent between full dose WFBP images and reduced dose SAFIRE images. Additionally, SAFIRE can reduce spiral artifacts by using iterations going back and forth between image space and raw data space.

A Model Observer evaluation showed that equivalent low contrast detectability can be achieved with 54% to 60% less dose using SAFIRE at highest noise reduction strength for thin (0.6 mm) reconstruction slices in simulated body and head phantoms for low contrast objects with different contrasts.

Images reconstructed with SAFIRE are not intended to be evaluated with syngo Osteo CT or syngo Calcium Scoring.

6. Substantial Equivalence:

Siemens Computed tomography X-ray systems, configured with software version SOMARIS/7 including SAFIRE are substantially equivalent to the following medical device in commercial distribution

Predicate Device Name	FDA Clearance Number	FDA Clearance Date
SOMATOM Definition Flash	***K082220***	***10/10/2008***

7. Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device

SAFIRE is an option within the image reconstruction module of the CT operating system SOMARIS/7 that can be selected by the user in addition to conventional image reconstruction technique (Weighted Filtered Back Projection). It improves image quality and allows for radiation dose reduction. The iterative steps include the validation of current images compared with measured raw data, and reconstruction of differences to an updated image, which is added to the previous image.

8. Verification and Validation

Non clinical tests were conducted for SAFIRE software package during product development. Additionally, a Model Observer evaluation showed that equivalent low contrast detectability can be achieved with 54% to 60% less dose using SAFIRE at highest strength for thin reconstruction slices in body and in head region compared to weighted filtered backprojection (WFBP). At the same time phantom measurements showed that high contrast resolution and pixel noise in the images is equivalent for full dose WFBP images and SAFIRE images acquired with reduced dose.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria.

Additionally the iterative reconstruction technique was evaluated in clinical environment. The results show that the use of up to 60% less radiation dose compared to today's standard scan techniques in combination with the use of SAFIRE provides images with the same results in terms of pixel noise and spatial resolution. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

The reduction of spiral artifacts was validated in clinical images and in simulations with established image quality phantoms.

9. General Safety and Effectiveness Concerns

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

10. Conclusion as to Substantial Equivalence

Siemens Computed tomography X-ray systems, configured with software version SOMARIS/7 including SAFIRE are intended for the same indications for use as the predicate. device

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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Mrs. Alicia Bustos-Juergensen
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51 Valley Stream Parkway, E-50
MELVERN PA 19355-1406

Re: K103424
Trade/Device Name: Safire
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 27, 2011
Received: October 28, 2011

Dear Mrs. Bustos-Juergensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K103424

Device Name: ***SAFIRE***

Indications for Use:

SAFIRE is a CT reconstruction software. The end user can choose to apply either SAFIRE or the weighted filter back-projection (WFBP) to the acquired raw data.

Depending on the clinical task, patient size, anatomical location, and clinical practice, the use of SAFIRE can help to reduce radiation dose while maintaining Pixel noise, low contrast detectability and high contrast resolution. Phantom measurements showed that high contrast resolution and pixel noise are equivalent between full dose WFBP images and reduced dose SAFIRE images. Additionally, SAFIRE can reduce spiral artifacts by using iterations going back and forth between image space and raw data space.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103424